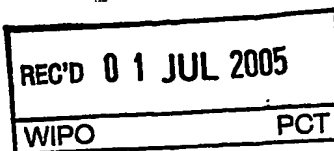


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference P200300476 WO	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/DK2004/000260	International filing date (<i>day/month/year</i>) 07.04.2004	Priority date (<i>day/month/year</i>) 11.04.2003	
International Patent Classification (IPC) or national classification and IPC A61M16/04			
Applicant AMBU AS ET AL.			
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 8 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. <input checked="" type="checkbox"/> <i>sent to the applicant and to the International Bureau</i> a total of 7 sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).			
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input checked="" type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application			
Date of submission of the demand 11.02.2005	Date of completion of this report 04.07.2005		
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Kroeders, M Telephone No. +31 70 340-1967	



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000260

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

2-25	as originally filed
1	received on 26.07.2004 with letter of 12.07.2004

Claims, Numbers

1-30	received on 11.02.2005 with letter of 11.02.2005
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Drawings, Sheets

1/16-16/16	as originally filed
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- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/DK2004/000260

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 3, 6, 8

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 3, 6, 8

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/DK2004/000260

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
 - ☒ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1, 2, 4, 5, 7, 9-30
	No: Claims	-
Inventive step (IS)	Yes: Claims	1, 2, 4, 5, 7, 9-30
	No: Claims	-
Industrial applicability (IA)	Yes: Claims	1, 2, 4, 5, 7, 9-30
	No: Claims	-

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/DK2004/000260

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 3, 6 and 8 were not searched in view of Article 17(2)(a)(ii) PCT and therefore no substantive examination can be performed.

Re Item IV

Lack of unity of invention

The separate inventions/groups of inventions are:

Group 1; claims 1-27 and 30

A laryngeal mask, comprising:

- A) at least one airway tube
- B) a mask portion, delimited by
- C) a cuff, specified by
 - C1) a circumferential closing joint
- D) parts A), B) and C) formed integrally

Group 2, claims 28 and 29

A laryngeal mask, comprising:

- A) at least one airway tube
- B) a mask portion, delimited by
- C) a cuff, specified by
 - C2) specific sealing properties of the cuff

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

In order that an International Application may contain more than one invention, the inventions defined in the application must form "a group", namely they should be so linked, as to form a single general inventive concept (see Rule 13.1 PCT). This inventive concept

finds expression in the independent claims according to the different inventions in terms of the same or corresponding special technical features. The definition "special technical features" refers to the features which, in the independent claims, involve an inventive step over the prior art.

In the present case the common or corresponding features of independent claims 1, 18, 27 and 28 are airway tube A), mask portion B) and cuff C), which are disclosed in combination in the documents cited in the search report and are therefore not only not involving an inventive concept over the prior art, but are not even new.

The features of method claim 18 and use claim 27 are consistent with the features of claim 1. The remaining features of independent claims 1 and 28, namely the integral forming of the airway tube and mask portion D) and specific sealing properties of the cuff C2) are different and have different purposes.

Therefore the application is considered to encompass 2 different, separate inventions, contrary to the requirements of Rule 13.1 PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Regarding the claims of group 1

1.1 Document US-A1-2003/037790, which is considered to represent the most relevant state of the art to the subject-matter of claim 1, discloses (the references in parenthesis applying to this document):

- A laryngeal mask (100) comprising
 - an airway tube (410) having a lumen; and
 - a mask portion (419),
said mask portion (419) comprising
 - an inflatable cuff (430); and
 - an intermediary portion forming a transition (423) from said airway tube (410)

to said inflatable cuff (430),
wherein the airway tube (410) and the intermediary portion are integrally
moulded, and in that the inflatable cuff (430) has a first peripheral edge and a
second peripheral edge (15) connected by a joint (16, 17).

The subject-matter of claim 1 differs from this disclosure in that the airway tube,
intermediary portion and cuff are all integrally moulded.

The subject-matter of claim 1 is therefore novel (Article 33(2) PCT).

The differentiating feature has the purpose of eliminating the risk of the laryngeal
mask separating in use.

None of the prior art documents as currently available disclose the same features for
the same purpose.

1.2 Independent claims 18 and 27

Claims 18 and 27 relate to a method of manufacturing a laryngeal mask comprising
the features of claim 1.

1.3 Claims 2, 4, 5, 7, 9 to 17, 19 to 26 and 30 are dependent on claims 1 and 18 respectively and as such also meet the requirements of the PCT with respect to novelty and inventive step.

2 Regarding the claims of group 2:

Document US-B1-6422239, which is considered to represent the most relevant state
of the art to the subject-matter of claim 28, discloses (the references in parenthesis
applying to this document):

a laryngeal mask (100) comprising at least one airway tube (410) and a mask portion (419), which mask portion comprises a top face (423) and a bottom face (422), said bottom face (422) comprising a lumen that communicates with the tube interior, and said top face (423) comprising a closed transition face, said mask portion (419) being at least on the bottom face (422) in the periphery delimited by an inflatable cuff (430),
wherein the cuff of the mask portion comprises means for abutment against a wall of a pharynx opposite a laryngeal opening for providing a tight connection of the mask portion and the laryngeal opening;
and that passages are formed between these abutment means and the top face of the mask portion

The subject-matter of claim 28 differs from this disclosure in that the abutment means are inflatable.

The abutment means disclosed in document US-B1-6439232 are inflatable, but with the purpose of closing any existing passages. Thus, none of the prior art as currently available discloses the same features for the same purpose.

Claim 29 is dependent on claim 28 and as such also meets the requirements of the PCT with respect to novelty and inventive step.

Laryngeal mask and method for the manufacture thereof

The invention relates to a laryngeal mask comprising at least one airway tube and a mask portion, said mask portion comprising a top face and a bottom face, said bottom face comprising a lumen that communicates with the tube interior, and said top face comprising a closed transition face; and wherein the mask portion is delimited in its periphery by an inflatable cuff at least on the bottom face.

Moreover, the invention relates to a method of manufacturing a laryngeal mask comprising at least one airway tube and a mask portion, said mask portion comprising a top face and a bottom face, said bottom face comprising a lumen that communicates with the tube interior, and said top face comprising a closed transition face; and wherein the mask portion is delimited in its periphery by an inflatable cuff at least on the bottom face.

EP-1 259 595 discloses the manufacture of laryngeal masks by means of rotational moulding, and wherein exclusively the mask portion as such is manufactured in that process.

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From EP-9 35 971 and EP 922 465 it is known to manufacture the mask portion by blow moulding.

Laryngeal masks are used in connection with the establishment of passage of air to the respiratory tracts, while simultaneously the air passage to the oesophagus is blocked. The laryngeal mask is shaped such that its lumen within the mask portion as such faces towards the laryngeal opening, and wherein there is provided an inflatable elliptical cuff around that lumen that forms a seal around the laryngeal opening. To the cuff there is a tubular connection that is connected to a balloon part and a valve, and by which the peripheral cuff of the mask is inflated thereby ensuring a tight abutment of the

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Amended claims

1. A laryngeal mask (1) comprising

- an airway tube (2) having a lumen (7); and
- 5 - a mask portion (3),

said mask portion (3) comprising

- an inflatable cuff (9); and
- an intermediary portion forming a transition (8) from said airway tube (2) to said inflatable cuff (9),

10 **characterised in that the airway tube (2) and the intermediary portion are integrally moulded, and in that the inflatable cuff (9) has a first peripheral edge integrally moulded with said intermediary portion, and a second peripheral edge (15) connected to said intermediary portion by a joint (16, 17).**

15

2. A laryngeal mask according to claim 1, **characterised in that in general the inflatable part of the wall thickness of the cuff is smaller than the general wall thickness of the airway tube (2).**

20 3. A laryngeal mask according to claim 2, **characterised in that the wall thickness of the inflatable part of the of the cuff is comprised within a closed first interval (111) having lower and upper values a,b and in that the wall thickness of the airway tube (2) is comprised within a closed second interval having lower and upper values c, d and in that the upper value d exceeds the**
25 **upper value.**

30

4. A laryngeal mask according to any one of claims 1, 2 or 3, **characterised in that the outer contour of the inner circumference of the cuff (9) is essentially elliptical, drop-shaped, annularly extending or a variety thereof.**

5. A laryngeal mask according to any one of claims 2-4, **characterised in** that the general wall thickness of the intermediary portion of the mask portion (3) is smaller than the general wall thickness of the airway tube (2), and larger than the general wall thickness of the cuff (9).

5

6. A laryngeal mask according to any one of claims 2-6, **characterised in** that the wall thickness of the intermediary portion of the mask portion (3) is comprised within a third interval whose lower limit is larger than a.

10 7. A laryngeal mask according to any one of claims 2-6, **characterised in** that the cuff (9), the intermediary portion of the mask portion (3) and/or the airway tube (2) has/have sections of a larger or smaller wall thickness than the general wall thickness of these parts.

15 8. A laryngeal mask according to claim 7, **characterised in** that the wall of the cuff (9) exhibits varying material thicknesses which comprised within the first interval (111).

20 9. A laryngeal mask according to any one of the preceding claims, **characterised in** that the laryngeal mask further comprises a rigid tubing (114) in extension of the airway tube (2) which is completely or partially enclosed by an outer jacket (117) configured as an integral part of the airway tube (2).

25 10. A laryngeal mask according to claim 9, **characterised in** that the rigid tubing (114) comprises guides in its surface, eg grooves.

30 11. A laryngeal mask according to any one of the preceding claims, **characterised in** that the airway tubing (2) comprises reinforcing ribs (22) that are integral with the airway tube (2) and axially parallel with the central axis thereof.

12. A laryngeal mask according to any one of the preceding claims, **characterised in** being manufactured in an injection moulding process and from an elastic polymer material.
- 5
13. A laryngeal mask according to any one of the preceding claims, **characterised in** that the airway tube (2) comprises at least one sensory indicator bead (10) comprising ribs on the outer face of the tube (2).
- 10
14. A laryngeal mask according to any one of the preceding claims, **characterised in** that the mask portion (3) comprises an additional inflatable bellows (11) arranged on or constituting an integral part of a top face (4) of the intermediary portion of the mask portion (3).
- 15
15. A laryngeal mask according to any one of the preceding claims, **characterised in** that the cuff (9) of the mask portion (3) comprises at least two inflatable lateral bellows (12) that are arranged on the top face (4) of the mask and essentially in parallel with the longitudinal axis of the cuff.
- 20
16. A laryngeal mask according to any one of the preceding claims, **characterised in** that at least the mask portion (3) is coated with a lubricant and/or an antibacterial agent.
17. A laryngeal mask according to any one of the preceding claims, **characterised in** that the closed transition face (8) comprises reinforcing ribs.
- 25
18. A method of manufacturing a laryngeal mask (1) comprising
- an airway tube (2) having a lumen (7); and
 - a mask portion (3),
- 30
- said mask portion (3) comprising

- an inflatable cuff (9); and
- an intermediary portion forming a transition (8) from said airway tube (2) to said inflatable cuff (9),

said process comprising

- 5 - injection moulding of the airway tube (2), the intermediary portion and the cuff (9) having an annularly extending opening (13) between a second peripheral edge (15) of said cuff (9) and said intermediary portion integrally in a closed mould part (101) in a first step,
- 10 - ejecting the airway tube (2), the intermediary portion and the cuff (9) having the annularly extending opening (13) from the mould (101) in a second step,
- providing a closed inflatable cuff (9) by closing of the annularly extending opening (13) by assembling the second peripheral edge (15) with said intermediary portion by a joint (16,17).

15

19. A method according to claim 18, characterised in that the distance between the second peripheral edge (15) and the intermediary portion at the annularly extending opening (13) is 1-8 mm.

20 20. A method according to claim 18 or 19, characterised in

- 25 - that liquid polymer material is injected into a closed mould (101) at a first pressure and a first temperature, wherein the mould (101) comprises at least one core (102) for providing the inner cavity in tube and mask portions, wherein the mould (101) also comprises two first mould parts, an upper first mould part (104) and a lower first mould part (105), whose interfaces (106) comprise a first interface (107) that is situated in the area corresponding to a lower face (5) of the mask and movable perpendicular to each other's interface (107); and
- 30 wherein the mould (101) also comprises two further second mould parts (108), whose second movement pattern is perpendicular to the movement line of the first mould part;

- that the lower first mould part (105) is moved away from the upper mould part (104);
 - that the two second mould parts (108) are moved away from each other by use of second movement pattern;
 - 5 - that the core (102) is subsequently moved in the same direction as the lower first mould part (105); and that
 - the laryngeal mask (1) is finished by ejection from the mould and closing of the annularly extending opening (13).
- 10 21. A method according to claim 20, characterised in that the entire or portions of the surface of the core (102) is/are rough.
22. A method according to any one of claims 18-21, characterised in that the periphery of the mask portion is formed by an upper and a lower
- 15 periphery configured by a tongue/groove arrangement, also known as a male/female arrangement, that is subsequently assembled against each other, eg by a gluing process for providing an essentially closed peripheral cuff (9).
- 20 23. A method according to any one of claims 18-22, characterised in that a rigid tubing (114) is arranged in extension of the airway tubing (2) to the effect that an outer jacket configured as an integral part of the airway completely or partially encloses the outer faces of the rigid tubing (114).
- 25 24. A method according to claim 23, characterised in the airway tube (2) and the mask portion (3) are moulded around the rigid tubing (114).
25. A method according to claim 24, characterised in that the airway tube (2), the mask portion (3) and the rigid tubing (114) are manufactured from the
- 30 same polymer material.

26. A method according to any one of claims 18-25, **characterised in that** a tube (18) is subsequently mounted on the peripheral cuff (9) of the laryngeal mask (1), which tube (18) is at the other end provided with a valve (19) and a pilot balloon (20).

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27. Use of the method according to claims 18-26 for the manufacture of a laryngeal mask according to claims 1-17.

10 28. A laryngeal mask (1') comprising at least one airway tube (2') and a mask portion (3'), which mask portion (3') comprises a top face (4') and a bottom face (5'), said bottom face (5') comprising a lumen (6') that communicates with the tube (2') interior (7'), and said top face (4') comprising a closed transition face (8'), said mask portion (3') being at least on the bottom face in the periphery delimited by an inflatable cuff (9'), **characterised in that the**
15 cuff (9') of the mask portion (3') comprises inflatable means for abutment against a wall of a pharynx opposite a laryngeal opening for providing a tight connection of the mask portion and the laryngeal opening; and that passages are formed between these abutment means and the top face (4') of the mask portion.

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29. A laryngeal mask (1') according to claim 28, **characterised in that the** cuff (9') of the mask portion (3') comprises at least two inflatable lateral bellows (12') that are arranged on the top face (4') of the mask (1') and are symmetrical about a longitudinal axis of the cuff (9').

25

30. A laryngeal mask (1) according to any one of claims 1-17, **characterised in that the** cuff (9) comprises a reinforced section (23) foremost on the top face of the cuff (9).